UNITED STATES DISTRICT COURT OF THE SOUTHERN DISTRICT OF TEXAS BROWNSVILLE DIVISION

SAN JUANA MUNOZ	§	
	§	
	§	
Plaintiff,	§	
	§	
v.	§	**Civil Cause No. 19-123**
	§	
ETHICON, INC., d/b/a ETHICON WOMEN'S HEALTH AND UROLOGY & JOHNSON & JOHNSON	§	
	§	
	§	
	§	
Defendants.	§	**JURY TRIAL DEMANDED**

PLAINTIFF'S ORIGINAL COMPLAINT

TO THE HONORABLE UNITED STATES DISTRICT COURT:

COMES NOW Plaintiff, San Juana Munoz by and through her counsel, and bring this Complaint against the Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter jointly referred to as "Defendants") as follows:

NATURE OF CASE

1. This is an action for damages suffered by San Juana Munoz ("Plaintiff") as a direct and proximate result of Defendants' wrongful contact in connection with the development, design, manufacture, marketing, distribution and selling of Defendants' Pelvic Repair System Products, including the Gynecare TVT Obturator System, which was implanted in Plaintiff's body to treat the medical conditions, pelvic organ prolapse and stress

urinary incontinence. Pursuant to Texas Rules of Civil Procedure Rule 190, Plaintiff intends discovery to be conducted under Level 2 as described in Rule 190.3.

2. Plaintiff, by her undersigned counsel, brings this action against Defendants related to the design, manufacture, marketing, distribution, and sale of Defendants' Pelvic Sling System Products, including the Gynecare TVT Obturator System. This action is for compensatory, equitable, injunctive, and declaratory relief. Plaintiff is making the following allegations based upon her individual personal knowledge as to her own acts, upon information and belief, and upon her attorneys' investigative efforts as to Defendants' actions and misconduct, and alleges as follows:

PARTIES

3. Plaintiff San Juana Munoz is and was, at all times material, a resident and citizen of the State of Texas, County of Cameron, and City of Brownsville.

4. Defendant Johnson & Johnson ("Johnson & Johnson") is a New Jersey Corporation, with its worldwide headquarters and principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson is a citizen and resident of New Jersey.

5. Defendant Ethicon, Inc. d/b/a Ethicon Women's Health and Urology ("Ethicon") is a New Jersey corporation with its principal place of business in Somerville, New Jersey. Ethicon is a citizen and resident of New Jersey. All acts and omissions of Ethicon as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership. Ethicon is a subsidiary of Johnson & Johnson. Defendant Ethicon, Inc. d/b/a

Ethicon Women's Health and Urology can be served at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

VENUE AND JURISDICTION

6. This Court has jurisdiction over the subject matter of this action based on diversity of citizenship pursuant to 28 U.S.C. § 1332. Plaintiff is a citizen of Texas and Defendants are citizens of New Jersey, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

7. Venue in this action is proper in this district pursuant to 28 U.S.C. § 1391(a), because the Plaintiff is a resident of Texas and a substantial number of the events, actions, and omissions giving rise to Plaintiff's claim occurred in this district. At all times material hereto, Johnson & Johnson is a for profit corporation authorized to and doing substantial business in this district.

8. At all times material hereto, Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold, and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Pelvic Sling System Product at issue in this matter. By said activities, Defendants' Pelvic Sling System Products, including but not limited to the Gynecare TVT Obturator System®, are placed into the stream of commerce throughout the United States, including within the State of Texas.

9. Defendants are subject to personal jurisdiction in the U.S. District Court for the District of Southern Texas as Defendants systematically and continually conduct business in this District, and Defendants conduct business throughout the United States, including in Texas.

DEFENDANTS' PELVIC MESH PRODUCTS

10. At all times material to this action, Defendants have designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic sling system products, which are delineated below. These products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. Each of these products were cleared for sale in the United States after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug, and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy. Plaintiff was implanted with Ethicon Inc.'s Gynecare TVT Obturator system (hereinafter referenced to as "Pelvic Sling System Product" or "Product").

FACTUAL BACKGROUND

11. On or about May 11, 2005, at Valley Regional Medical Center in Brownsville, Texas, Plaintiff's physician, Dr. James Carleo, implanted Ethicon, Inc.'s Gynecare TVT Obturator System to treat stress urinary incontinence.

12. Prior to Plaintiff's surgery, her treating physician, as well as Plaintiff, were exposed to the advertising and marketing campaign directed by Defendants.

13. Plaintiff and her physician, either through direct promotional contact with Defendants' Sales Representatives, Lab Faculty, through word-of-mouth with other healthcare providers, and/or through promotional materials, received the information Defendants intended Plaintiff and her physician to receive and/or review, claiming that the Pelvic Mesh Products were safe and effective for use in the treatment of pelvic organ prolapse and stress urinary incontinence.

14. Plaintiff began experiencing severe pelvic pain, urinary tract infections, vaginal bleeding, mesh erosion, vaginal shortening, vaginal tightening,

15. Plaintiff returned to her physician due to complications and problems attributed to Ethicon Inc.'s Pelvic Sling System Product.

16. Due to these complications and problems attributed to the Ethicon, Inc.'s Pelvic Sling System Product, on or about July 5, 2017, at Valley Baptist – Brownsville in Brownsville, Texas, Plaintiff's physician, Dr. Henry Ruiz, MD, completely excised the Ethicon, Inc.'s Gynecare TVT Obturator System.

17. As a direct and proximate result of the use of the Ethicon, Inc. Pelvic Sling System Product, Plaintiff suffered, and continues to suffer, serious bodily injury and harm, including, but not limited to mental anguish, chronic pain, , and urinary tract infections. Plaintiff has also suffered financial or economic loss, including but not limited to, obligations for medical services and expenses.

18. As a direct and proximate result of the use of the Ethicon, Inc.'s Pelvic Sling System Product, Plaintiff incurred, and continues to incur, medical expenses to treat her injuries and condition.

19. As a direct and proximate result of the use of the Ethicon, Inc.'s Pelvic Sling System Product, Plaintiff continues to receive medical treatment and could potentially undergo further surgeries to repair damage caused by the sling.

20. Ethicon, Inc. develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells and otherwise engages in all activities that are part and parcel of the sale and distribution of their Pelvic Sling System Product for the treatment of medical

conditions in the female pelvis, primarily pelvic organ prolapse, and stress urinary incontinence.

21. At all relevant times, transvaginal meshes were used to treat pelvic organ prolapse and stress urinary incontinence.

22. A pelvic organ prolapse occurs when a pelvic organ, such as the bladder, bowels, rectum, small intestine, and uterus, drops or "prolapses", from its normal position and pushes against the wall of the vagina. Prolapses can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time.

23. Stress urinary incontinence is a type of incontinence caused by leakage of urine during moments of physical stress. It affects 20-40% of all women.

24. Surgical mesh, including transvaginal mesh, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material and absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most transvaginal meshes are comprised of non-absorbable synthetic polypropylene. Upon information and belief, the Pelvic Mesh Product is comprised of a synthetic, petroleum-based mesh.

25. Ethicon Inc.'s Pelvic Sling System Product contain monofilament polypropylene mesh and/or collagen and were and are utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the relevant Plaintiff is biologically incompatible with human tissue and promotes a negative

immune response in a large subset of the population implanted with Ethicon Inc.'s Pelvic Sling System Product. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Ethicon's collagen product's cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Ethicon's collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign material derived from animal tissue. Animal collagen is harsh upon the female pelvic tissue. It hardens in the body. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

26. In 1996, the FDA cleared the first mesh product for use in the treatment of stress urinary incontinence (SUI). These mesh products include transvaginal mesh, including the Gynecare TVT Obturator System, which was manufactured, marketed, and distributed by Ethicon, Inc. These products are approved by the FDA under the Section 510(k) of the Medical Device Amendment to the Food, Drug, and Cosmetics act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the Product.

27. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three-year period relating to pelvic mesh

products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendants are one of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "rare".

28. On July 13, 2011, the FDA issued a safety communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare".

29. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA… Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening, and vaginal pain".

30. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

31. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk".

32. Contemporaneously with the Safety Communication, the FDA released a publication titled 'Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper". In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not

experienced by patients who undergo traditional surgery without mesh."

33. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original).

34. The FDA White Paper further stated that "these products are associated with serious adverse events … Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

35. In its White Paper, the FDA advises doctors to, inter alia, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

36. The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

37. Defendants knew or should have known about the Product's risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

38. Defendants knew or should have known that the Product unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

39. The scientific evidence shows that the material from which Defendants' Product is made is biologically incompatible with human tissue and promotes a negative immune

response in a large subset of the population implanted with the Product, including the Plaintiff.

40. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by the Plaintiff.

41. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code". "Material Fragmentation" is defined as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction". The Product was unreasonably susceptible to degradation and fragmentation inside the body.

42. In 2016, the FDA reclassified surgical mesh devices, such as the one manufactured by the Defendants and implanted within the Plaintiff, to class III devices which are defined as high risk devices. All manufactures were required to submit premarket approval applications which is the agencies

43. On April 16, 2019, the FDA released a press announcement ordering all manufacturers of surgical mesh products intended for treating pelvic organ prolapse and to stop selling and distributing their products within the United States immediately. A statement regarding the marketing, selling, manufacturing, and distributing in the United States from Jeffrey Suren, M.D:

> "In order for these mesh devices to stay on the market, we determined that we needed evidence that they worked better than surgery without the use of mesh to repair POP. That evidence was lacking in these premarket applications, and we couldn't assure women that these devices were safe and effective long term," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "Patient safety is our highest priority, and women must have access to safe medical devices that provide relief from symptoms and better management of their medical conditions. The FDA has committed to taking forceful new

> actions to enhance device safety and encourage innovations that lead to safer medical devices, so that patients have access to safe and effective medical devices and the information they need to make informed decisions about their care."

44. The Product was unreasonably susceptible to shrinkage and contraction inside the body.

45. The Product was unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

46. The Product has been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

47. Defendants omitted the risks, dangers, defects, and disadvantages of the Product, and advertised, promoted, marketed, sold and distributed the Product as a safe medical device when Defendants knew or should have known that the Product was not safe for their intended purposes, and that the Product would cause, and did cause, serious medical problems, and in some patients, including the Plaintiff, catastrophic injuries.

48. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Product has high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

49. The specific nature of the Product's defects includes, but is not limited to, the

following:

a) The use of polypropylene and collagen material in the Product and the immune reactions that result from such material, causing adverse reactions and injuries;

b) The design of the product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d) The use and design of arms and anchors in the Product, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e) The propensity of the Product to "creep", or to gradually elongate and deform when subject to prolonged tension inside the body;

f) The inelasticity of the Product, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g) The propensity of the Product for degradation or fragmentation over time,

which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen products to disintegrate after implantation in the female pelvic, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k) The harshness of cross-linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

50. The Product is also defective due to Defendants' failure to adequately warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a) The Product's propensities to contract, retract, and/or shrink inside the body;

b) The Product's propensities for degradation, fragmentation and/or creep;

c) The Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d) The rate and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Product;

f) The risk of chronic infections resulting from the Product;

g) The risk of permanent vaginal or pelvic scarring as a result of the Product ;

h) The risk of recurrent, intractable pelvic pain, and other pain resulting from the Product;

i) The need for corrective or revision surgery to adjust or remove the Product;

j) The severity of complications that could arise as a result of implantation of the Product;

k) The hazards associated with the Product;

l) The Product's defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r) Complete removal of the Product may not be possible and may not result in

complete resolution of the complications, including pain.

51. Defendants have underreported information about the propensity of the Product to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Product through various means and media.

52. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Product.

53. Defendants failed to design and establish a safe, effective procedure for removal of the Product exists.

54. Feasible and suitable alternatives to the Product have existed at all times relevant that do not present the same frequency or severity of risks as does the Product.

55. The Product was at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

56. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Product and the aftercare of patients implanted with the Product.

57. The Product implanted in the Plaintiff was in the same or substantially similar condition as they were they left Defendants' possession, and in the condition directed by and expected by Defendants.

58. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Product include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation,

dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

59. In many cases, including the Plaintiff, the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

60. The medical and scientific literature studying the effects of Defendants' mesh product has examined each of these injuries, conditions, and complications, and has reported that they are casually related to the Product.

61. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

62. At all relevant times herein, Defendants continued to promote the Product as safe and effective even when no clinical trials had been done supporting long-or short-term efficacy.

63. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Product.

64. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Product.

65. The Product as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

66. As a result of having the Product implanted in her, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

CAUSE OF ACTION
COUNT 1: NEGLIGENCE

67. Paragraphs 1-66 of this complaint are hereby incorporated by reference as if fully set forth herein.

68. Defendants had a duty to individuals, including the Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Product.

69. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging, and selling the Product. Defendants breached their aforementioned duty by:

a) Failing to design the Product as to avoid an unreasonable risk of harm to women in whom the Product was implanted, including the Plaintiff;

b) Failing to manufacture the Product so as to avoid an unreasonable risk of harm to women in whom the Product was implanted, including the Plaintiff;

c) Failing to use reasonable care in the testing of the Product so as to avoid an unreasonable risk of harm to women in whom the Product was implanted,

including the Plaintiff;

d) Failing to use reasonable care in inspecting the Product so as to avoid an unreasonable risk of harm to women in whom the Product was implanted, including the Plaintiff; and

e) Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging, and/or selling the Product.

70. The reasons that Defendants' negligence caused the Product to be unreasonably dangerous and defective include, but are not limited to:

a) The use of polypropylene material and/or collagen material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b) The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d) The use and design of arms and anchors in the Product, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e) The propensity of the Product to "creep" or to gradually elongate and deform when subject to prolonged tension inside the body;

f) The inelasticity of the Product, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g) The propensity of the Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain, and other adverse reactions;

j) The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k) The harshness of cross-linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

71. Defendants also negligently failed to warn or instruct the Plaintiff and/or her

health care providers of subjects including, but not limited to, the following:

a) The Product's propensities to contract, retract, and/or shrink inside the body;

b) The Product's propensities for degradation, fragmentation and/or creep;

c) The Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d) The rate and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Product;

f) The risk of chronic infections resulting from the Product;

g) The risk of permanent vaginal or pelvic scarring as a result of the Product ;

h) The risk of recurrent, intractable pelvic pain, and other pain resulting from the Product;

i) The need for corrective or revision surgery to adjust or remove the Product;

j) The severity of complications that could arise as a result of implantation of the Product;

k) The hazards associated with the Product;

l) The Product's defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the

Product makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r) Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

72. As a direct and proximate result of Defendants' negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services, and expenses, lost income, and other damages.

73. WHEREFORE, Plaintiff demands judgement against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

74. Plaintiff incorporates by reference paragraphs 1-73 of this Complaint as if fully set forth herein.

75. The Product implanted in the Plaintiff was not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated,

the Product's design defects include, but are not limited to:

a) The use of polypropylene material and/or collagen material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries

b) The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d) The use and design of arms and anchors in the Product, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e) The propensity of the Product to "creep" or to gradually elongate and deform when subject to prolonged tension inside the body;

f) The inelasticity of the Product, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g) The propensity of the Product for degradation or fragmentation over time,

which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain, and other adverse reactions;

j) The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k) The harshness of cross-linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

76. As a direct and proximate result of the Product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

77. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling defective products. Defendants' actions are in

violation of Tex. Civ. Prac. & Rem. Code § 82.005(a).

78. WHEREFORE, Plaintiff demands judgement against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

79. Plaintiff incorporates by reference paragraphs 1-78 of this Complaint as if fully set forth herein.

80. The Product implanted in the Plaintiff was not reasonably safe for their intended uses and were defective as described herein as a matter of law with respect to their manufacture, in that they deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the Plaintiff.

81. Defendants' Product is inherently dangerous a defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

82. The Product creates risk to the health and safety of the patients, including the Plaintiff, that are fare more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Product.

83. Defendants have intentionally and recklessly manufactured the Product with wanton and willful disregard for the rights and health of the Plaintiff, with malice, placing

their economic interests above the health and safety of the Plaintiff.

84. As a direct and proximate result of the Product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

85. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling a defective product. Defendants' actions are violations of Tex. Civ. Prac. & Rem. Code § 82.003 (a)(6)

86. WHEREFORE, Plaintiff demands judgement against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

87. Plaintiff incorporates by reference paragraphs 1-86 of this complaint as if fully set forth herein.

88. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the proper candidates and the safest and most effective methods of implantation of the Product.

89. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the risks and benefits of the Defendants' Product, given the Plaintiff's conditions and need for information.

90. The Product implanted in the Plaintiff is not reasonably safe for its intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a) The Product's propensities to contract, retract, and/or shrink inside the body;

b) The Product's propensities for degradation, fragmentation and/or creep;

c) The Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d) The rate and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Product;

f) The risk of chronic infections resulting from the Product;

g) The risk of permanent vaginal or pelvic scarring as a result of the Product ;

h) The risk of recurrent, intractable pelvic pain, and other pain resulting from the Product;

i) The need for corrective or revision surgery to adjust or remove the Product;

j) The severity of complications that could arise as a result of implantation of the Product;

k) The hazards associated with the Product;

l) The Product's defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r) Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

91. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' Product, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

92. As a direct and proximate result of the Product's aforementioned defects, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, economic loss and damages including, but not limited to medical expenses, lost income and/or other damages.

93. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling the defective product. Defendant is in violation of Tex. Civ. Prac. & Rem. Code § 82.003 (a) (4).

94. WHEREFORE, Plaintiff demands judgement against Defendants, and each of, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V: STRICT LIABILITY – DEFECTIVE PRODUCT

95. Plaintiff incorporates by reference paragraphs 1-94 of this Complaint as if fully set forth herein.

96. At the time Plaintiff's injuries, the Defendants' Product was defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiff, and the warning labels, and instructions were deficient.

97. The Defendants' Product is dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers, including Plaintiff and her healthcare providers.

98. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Product, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, consortium, comfort, economic damages, and other damages.

99. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling the defective product. Defendant is in violation of Tex. Civ. Prac. & Rem. Code § 82.003 (a) (6).

100. WHEREFORE, Plaintiff demands judgement against Defendants, and each of

them individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI: BREACH OF EXPRESS WARRANTY

101. Plaintiff incorporates by reference paragraphs 1-100 of this Complaint as if fully set forth herein.

102. Defendants made assurances as described herein to the general public, hospitals, and health care professionals that the Product is safe and reasonably fit for their intended purposes.

103. The Plaintiff and/or her heath care provider chose the Product based upon Defendants' warranties and representations as described herein regarding the safety and fitness of the Product.

104. The Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Product based upon Defendants' express warranties and guarantees that the Product is safe, merchantable, and reasonably fit for their intended purposes.

105. Defendants breached these express warranties because the Product implanted in the Plaintiff was unreasonably dangerous and defective as described herein and not as Defendants had represented.

106. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing said

Plaintiff's health and safety in jeopardy.

107. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

108. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling the defective product. Defendant is in violation of Tex. Civ. Prac. & Rem. Code § 82.003 (a) (5).

109. WHEREFORE, Plaintiff demands judgement against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys fees, and such further relief as the Court deems equitable and just.

COUNT VII: BREACH OF IMPLIED WARRANTY

110. Plaintiff incorporates by reference paragraphs 1-109 of this Complaint as if fully set forth herein.

111. Defendants impliedly warranted that the Product is merchantable and is fit for the ordinary purposes for which they were intended.

112. When the Product was implanted in the Plaintiff to treat her pelvic organ prolapse and/or stress urinary incontinence, the Product was being used for the ordinary purposes for

which they were intended.

113. The Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Product implanted in her.

114. Defendants breached these implied warranties of merchantability because the Product implanted in the Plaintiff were neither merchantable nor suited for their intended uses as warranted.

115. Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in the body of the Plaintiff, placing said Plaintiff's health and safety in jeopardy.

116. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

117. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling the defective product. Defendant is in violation of Tex. Civ. Prac. & Rem. Code § 82.003.

118. WHEREFORE, Plaintiff demands judgement against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory

damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII: FRADULENT CONCEALMENT

119. Plaintiff incorporates by reference paragraphs 1-118 of this Complaint as if fully set forth herein.

120. Throughout the relevant time periods, it was known or known to Defendants that their Product caused large numbers of complications that were not rare. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devise. It was known or knowable to Defendants that the safety and efficacy of the Product had not been proven with respect to, among other things, the product, its components, its performance and its method of insertion. It was known or knowable to Defendants that there was no evidence that the Product is safe and effective and, in fact the evidence that was known or knowable to Defendants that the Product is not safe and effective. Defendants continued to represent that the Product is safe and effective.

121. Despite what was known or knowable to Defendants about the lack of safety and efficacy of the Product through the relevant time periods, Defendants failed to disclose this information to the Plaintiff, her physicians, or to the public at large.

122. Despite this knowledge, Defendants continued to market and sell their Product and procedures as being safe and efficacious with evidence to the contrary.

123. At all times mentioned herein, Defendants, and each of them, had the duty and

obligation to disclose to Plaintiff and to her physicians, the true facts concerning the aforesaid Product, that is, that said Product is dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiff was implanted with Defendants' Product.

124. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Products because:

a) Defendants were in a superior position to know the true quality, safety and efficacy of the Defendants' Product;

b) Defendants knowingly made false claims about the safety and quality of the Defendants' Product in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c) Defendants fraudulently and affirmatively concealed the defective nature of the Defendants' Product from Plaintiff.

125. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Product.

126. At all times herein mentioned, Defendants, and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiff and her physicians, and therefore, Plaintiff, with the intent to defraud as herein alleged.

127. Defendants intentionally concealed and/or failed to disclose the true defective

nature of the Product so that Plaintiff would request and purchase the Defendants' Product, and that her healthcare providers would dispense, prescribe, and recommend the Defendants' Product, and Plaintiff justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Defendants' Product.

128. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the facts set forth above, and had they been aware of said facts, they would have acted as they did, that is, would not have reasonably relied upon said representations of safety and efficacy and utilized the Product for treatment of stress urinary incontinence and pelvic organ prolapse. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' Product and procedures for treatment of stress urinary incontinence and pelvic organ prolapse. This failure to disclose also resulted in the provision of incorrect and incomplete information to the Plaintiff.

129. As a direct and proximate result of this conduct, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

130. WHEREFORE, Plaintiff demands judgement against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XI: CONSTRUCTIVE FRAUD

131. Plaintiff incorporates by reference paragraphs 1-130 of this Complaint as if fully set forth herein.

132. Defendants are in a unique position of knowledge concerning the quality, safety, and efficacy of the Defendants' Product, which knowledge is not possessed by Plaintiff or her physicians, and Defendants thereby hold a position of superiority over Plaintiff and her physicians.

133. Despite their unique and superior knowledge regarding the defect nature of the Defendants' Product, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiff, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Defendants' Product, as compared to other products and forms of treatment.

134. For example, scientists in the recent study published in Obstetrics & Gynecology, August 2010, found that the complication was so high that the clinical trial was halted early.

135. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the Defendants' Product had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the Product.

136. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiff to prescribe and the medical community have relied upon Defendants' representations.

137. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and her medical providers and engaged in constructive fraud in their relationship with Plaintiff and her medical providers. Plaintiff reasonably relied on Defendants' representations.

138. As a proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, consortium, economic damages, and other damages.

139. WHEREFORE, Plaintiff demands judgement against Defendants, and each of them, individually, jointly, severally, and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XI: PUNITIVE DAMAGES

140. Plaintiff incorporates by reference paragraphs 1-145 of this Complaint as if fully set forth herein.

141. Defendants sold their Product to the healthcare providers of the Plaintiff and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Product were reasonably safe for implantation in the female pelvic area.

142. Defendants sold the Product to the Plaintiff's healthcare providers and other healthcare providers in the state of implantation and throughout the United States in spite of their knowledge that the Product can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore to set forth in this Complaint, thereby causing severe and

debilitating injuries suffered by the Plaintiff and numerous other women.

143. Defendants ignored reports from patients and healthcare providers throughout the United States and elsewhere of the Product's failures to perform as intended, which lead to the severe and debilitating injuries suffered by the Plaintiff and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Product's designs, or the processes by which the Product is manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the Product as safe and effective.

144. Defendants knew the Product is unreasonably dangerous in light of their risks of failure, pain, and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Product, as well as other severe and personal injuries where were permanent and lasting in nature.

145. Defendants withheld material information from the medical community and the public in general, including the Plaintiff, regarding the safety and efficacy of the Product.

146. Defendants knew and recklessly disregarded the fact that the Product caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

147. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Product.

148. Notwithstanding the foregoing, Defendants continue to aggressively market the Product to consumers, without disclosing the true risks associated with the Product.

149. Defendants knew of the Product's defective and unreasonably dangerous nature,

but continued to manufacture, market, distribute, and sell the Product so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff.

150. Defendants continue to conceal and/or fail to disclose to the public, including the Plaintiff, the serious complications associated with the use of the Product to ensure continued and increased sales of the Product.

151. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgement against Defendants, and each of them, individually, jointly, and severally and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

a) Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

b) Reasonable attorneys' fees;

c) The costs of these proceedings;

d) All ascertainable economic damages;

e) Medical monitoring damages;

f) Punitive damages;

g) Such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff specifically demands a trial by jury of all claims asserted in this Complaint.

Dated: July 5, 2019

Respectfully submitted,

/s/ Matthew R. McCarley
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